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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,506	08/10/2001	Oxana Ibraghimov-Beskrovnyaya	126881201600	8221

7590                  02/27/2002

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[REDACTED] EXAMINER

HADDAD, MAHER M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/830,506	IBRAGIMOV-BESKROVNAYA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Maher M. Haddad	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-29 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Maher Haddad, Art Unit 1644, Technology Center 1600.

#### ***Sequence Compliance***

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

3. The following is noted:

A) Independent claim 23 includes a recitation of “modulating cell-cell adhesion”. Dependent claim 25 recites that modulating is “prevents or inhibits cell-cell adhesion”, whereas dependent claim 28 recites that modulating is “promotion or enhancement of cell-cell adhesion”. These methods are mutually exclusive in that they reach opposing endpoints, and in that they employ distinct core structures *agonists* or *antagonists* to accomplish these mutually exclusive endpoints.

Consequently, the claims have been limited to either a method of *inhibiting cell-cell adhesion*, or a method of *enhancing cell-cell adhesion*, irrespective of the format of the claims.

B) Examiner considers claims 24 and 28 were intended to depend from claim 23 rather than claim 22.

***Election/Restrictions***

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-11 and 22, drawn to an isolated antibody and a hybridoma and a diagnostic kit.

Group II, claims 12 –15, drawn a recombinant polypeptide of polycystin.

Group III, claims 16-18, drawn to an isolated polynucleotide encoding polycystin and a host cell.

Group IV, claims 19-21, drawn to isolated polypeptide having an apparent molecular weight in the range of about 600 to about 800 Kd.

Group V, claims 23-27, drawn to a method for inhibiting cell-cell adhesion in a suitable tissue comprising delivering to the tissue *an antibody* that binds to the Ig-like domains of polycystin.

Group VI, claims 23-27, drawn to a method for inhibiting cell-cell adhesion in a suitable tissue comprising delivering to the tissue *an antisense polycystin DN*.

Group VII, claims 23-27, drawn to a method for inhibiting cell-cell adhesion in a suitable tissue comprising delivering to the tissue *a ribozymes* that recognize or cleave polycystin DNA.

Group VIII, claims 23, and 28-29, drawn to a method for enhancing cell-cell adhesion in a suitable tissue comprising delivering to the tissue *an antibody*.

Group IX, claims 23, and 28-29, drawn to a method for enhancing cell-cell adhesion in a suitable tissue comprising delivering to the tissue *a polynucleotide*.

Group X, claims 23, and 28-29, drawn to a method for enhancing cell-cell adhesion in a suitable tissue comprising delivering to the tissue *a polypeptide*.

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6. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Klinger et al. (US Pat. No.6,071,717) (see entire document).

Klinger et al., teach and claim anti-polycystin antibodies comprising PKD1 full-length, the carboxy terminal epitopes, as well as the transmembrane domains (the "antigenic peptide" of the claims 1-11) (see the entire document, also columns 25 and 26, lines 33-50 and 5-11 respectively).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

7. The application contains claims directed to the following patentably distinct species of the claimed Inventions I and II: wherein amino acid residues are:

- A. 2621 to 2710,
- B. 2734 to 3094,
- C. 3116 to 3300,
- D. 3364 to 3578,
- E. 3623 to 3688,
- F. 3710 to 3914,
- G. 3931 to 4046,
- H. 2166 to 2599,
- I. 4097 to 4302,
- J. 4148 to 4219,
- K. 4220 to 4302,
- L. 27 to 360,
- M. 843 to 1200,
- N. 1205 to 1625, or
- O. 1626 to 2136.

These species are distinct because different species differ in their amino acid sequences and thus have no common core structure.

Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.  
Patent Examiner  
Technology Center 1600  
February 27, 2002

PHILLIP GAMBEL  
PHILLIP GAMBEL, PH.D  
PRIMARY EXAMINER  
TECH CENTER 1600  
2/27/02